

AMENDMENT

In the Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

1-6. (Canceled)

7. (Currently amended) A method of stimulating an immune response in a vertebrate subject which comprises

(a) administering to the subject an effective amount of a first composition consisting essentially of a pharmaceutically acceptable excipient and a polynucleotide adsorbed to a cationic microparticle, wherein said polynucleotide comprises a coding sequence that encodes a hepatitis C virus (HCV) immunogen operably linked to control elements that direct the transcription and translation of said coding sequence *in vivo*, and further wherein the HCV immunogen is an immunogenic HCV E1E2 complex consisting of the contiguous sequence of amino acids depicted at positions 20-637 of SEQ ID NO:2, with the proviso that said polynucleotide does not encode an HCV immunogen other than the HCV E1E2 complex, wherein said HCV E1E2 complex is expressed *in vivo* to elicit an immune response; and

(b) subsequently administering parenterally a second composition comprising a pharmaceutically acceptable excipient and an immunogenic HCV E1E2 complex consisting of the sequence of amino acids depicted at positions 20-637 of SEQ ID NO:2, to elicit an immune response in the subject.

8. (Canceled)

9. (Original) The method of claim 7, wherein the cationic microparticle is formed from a polymer selected from the group consisting of a poly(α -hydroxy acid), a polyhydroxy butyric acid, a polycaprolactone, a polyorthoester, and a polyanhydride.

10. (Original) The method of claim 9, wherein the cationic microparticle is formed from a poly(α -hydroxy acid) selected from the group consisting of poly(L-lactide), poly(D,L-lactide) and poly(D,L-lactide-co-glycolide).

11. (Original) The method of claim 10, wherein the cationic microparticle is formed from poly(D,L-lactide-co-glycolide).

12-15. (Canceled)

16. (Previously presented) The method of claim 7, wherein said second composition further comprises an adjuvant.

17. (Original) The method of claim 16, wherein said adjuvant is a submicron oil-in-water emulsion capable of enhancing the immune response to the immunogenic HCV polypeptide, wherein the submicron oil-in-water emulsion comprises (i) a metabolizable oil, wherein the oil is present in an amount of 1% to 12% of the total volume, and (ii) an emulsifying agent, wherein the emulsifying agent is present in an amount of 0.01% to 1% by weight (w/v) and comprises polyoxyethylene sorbitan mono-, di-, or triester and/or a sorbitan mono-, di-, or triester, wherein the oil and the emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are about 100 nm to less than 1 micron in diameter.

18. (Original) The method of claim 17, wherein the submicron oil-in-water emulsion comprises 4-5% w/v squalene, 0.25-1.0% w/v polyoxyethylenesorbitan monooleate, and/or 0.25-1.0% sorbitan trioleate, and optionally, N-acetylmuramyl-L-alanyl-D-isoglutaminyl-L-alanine-2-(1'-2'-dipalmitoyl-*sn*-glycero-3-hydroxy phosphoryloxy)-ethylamine (MTP-PE).

19. (Original) The method of claim 17, wherein the submicron oil-in-water emulsion consists essentially of about 5% by volume of squalene; and one or more emulsifying agents

selected from the group consisting of polyoxyethylthylenesorbitan monooleate and sorbitan trioleate, wherein the total amount of emulsifying agent(s) present is about 1% by weight (w/v).

20. (Original) The method of claim 19, wherein the one or more emulsifying agents are polyoxyethylthylenesorbitan monooleate and sorbitan trioleate and the total amount of polyoxyethylthylenesorbitan monooleate and sorbitan trioleate present is about 1% by weight (w/v).

21. (Withdrawn) The method of claim 7, wherein said second composition further comprises a CpG oligonucleotide.

22. (Currently amended) A method of stimulating an immune response in a vertebrate subject which comprises:

(a) administering to the subject an effective amount of a first composition consisting essentially of a polynucleotide adsorbed to a cationic microparticle formed from poly(D,L-lactide-co-glycolide), wherein said polynucleotide comprises a coding sequence that encodes a hepatitis C virus (HCV) immunogen operably linked to control elements that direct the transcription and translation of said coding sequence *in vivo*, and further wherein the HCV immunogen is an HCV E1E2 complex consisting of the sequence of amino acids depicted at positions 20-637 of SEQ ID NO:2, with the proviso that said polynucleotide does not encode an HCV immunogen other than the HCV E1E2 complex, and wherein said HCV E1E2 complex is expressed *in vivo*; and

(b) subsequently administering parenterally an effective amount of a second composition to the subject, wherein the second composition comprises (i) an immunogenic HCV E1E2 complex consisting of the sequence of amino acids depicted at positions 20-637 of SEQ ID NO:2, (ii) an adjuvant, and (iii) a pharmaceutically acceptable excipient, to elicit an immune response in the subject.

23. (Original) The method of claim 22, wherein said adjuvant is a submicron oil-in-water emulsion capable of enhancing the immune response to the immunogenic HCV E1E2 complex in the second composition, wherein the submicron oil-in-water emulsion comprises (i) a

metabolizable oil, wherein the oil is present in an amount of 1% to 12% of the total volume, and
(ii) an emulsifying agent, wherein the emulsifying agent is present in an amount of 0.01% to 1% by weight (w/v) and comprises polyoxyethylene sorbitan mono-, di-, or triester and/or a sorbitan mono-, di-, or triester, wherein the oil and the emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are about 100 nm to less than 1 micron in diameter.

24. (Original) The method of claim 23, wherein the submicron oil-in-water emulsion comprises 4-5% w/v squalene, 0.25-1.0% w/v polyoxyelthylenesorbitan monooleate, and/or 0.25-1.0% sorbitan trioleate, and optionally, N-acetylmuramyl-L-alanyl-D-isogluatminyl-L-alanine-2-(1'-2'-dipalmitoyl-*sn*-glycero-3-hydroxy phosphoryloxy)-ethylamine (MTP-PE).

25. (Original) The method of claim 23, wherein the submicron oil-in-water emulsion consists essentially of about 5% by volume of squalene; and one or more emulsifying agents selected from the group consisting of polyoxyelthylenesorbitan monooleate and sorbitan trioleate, wherein the total amount of emulsifying agent(s) present is about 1% by weight (w/v).

26. (Original) The method of claim 25, wherein the one or more emulsifying agents are polyoxyelthylenesorbitan monooleate and sorbitan trioleate and the total amount of polyoxyelthylenesorbitan monooleate and sorbitan trioleate present is about 1% by weight (w/v).

27. (Withdrawn) The method of claim 23, wherein said second composition further comprises a CpG oligonucleotide.

28. (canceled)

29. (Canceled)